

NDA 21-229: Prilosec OTC™ ; Item 2 – Revised Draft Labeling (16 June 2003)  
Appendix 2.6 – Trial Sample Size Labeling

**NEW!**

**FREE** of new **Prilosec OTC™**  
STARTER KIT

Treats **Frequent**  
Heartburn!

NDC 37000-455-01

Treats **Frequent** Heartburn!

**Prilosec OTC™**

esomeprazole delayed-release  
tablet 20 mg / acid reducer

Call 1-800-755-4841  
Dist. by Procter & Gamble, Cincinnati, OH 45202  
Product of Sweden

Do not use if pouch  
is open or torn.  
**1 TABLET**

NDC 37000-455-01

Treats **Frequent** Heartburn!

**Prilosec OTC™**

esomeprazole delayed-release  
tablet 20 mg / acid reducer

Call 1-800-755-4841  
Dist. by Procter & Gamble, Cincinnati, OH 45202  
Product of Sweden

Do not use if pouch  
is open or torn.  
**1 TABLET**

**Experience the first couple of days of your 14-day course of treatment!**  
Follow samples with a 14-day course of treatment. Read label on back before use.

NDA 21-229; Prilosec OTC™; Item 2 – Revised Draft Labeling (16 June 2003)  
 Appendix 2.6 (Cont'd) – Trial Sample Size Labeling

<p><b>Drug Facts</b></p> <p><b>Active ingredient (in each tablet)</b>                  Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole).....Acid reducer</p>	<p><b>Drug Facts</b> (continued)</p> <p><b>if pregnant or breast-feeding</b>, ask a health professional before use. <b>Keep out of reach of children.</b> In case of overdose, get medical help or contact a Poison Control Center right away.</p>
<p><b>Use</b></p> <ul style="list-style-type: none"> <li>■ treats frequent heartburn (occurs <b>2 or more</b> days a week)</li> <li>■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect</li> </ul>	<p><b>Directions</b></p> <ul style="list-style-type: none"> <li>■ adults 18 years of age and older</li> <li>■ this product is to be used once a day (every 24 hours), every day for 14 days</li> <li>■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours</li> </ul>
<p><b>Warnings</b></p> <p><b>Allergy alert:</b> Do not use if you are allergic to omeprazole</p> <p><b>Do not use</b> if you have</p> <ul style="list-style-type: none"> <li>■ trouble or pain swallowing food</li> <li>■ vomiting with blood</li> <li>■ bloody or black stools</li> </ul> <p>These may be signs of a serious condition. See your doctor.</p>	<p><b>14-Day Course of Treatment</b></p> <ul style="list-style-type: none"> <li>■ swallow 1 tablet with a glass of water once a day before eating</li> <li>■ take every day for 14 days</li> <li>■ do not take more than 1 tablet a day</li> <li>■ do not chew or crush the tablets</li> <li>■ do not crush tablets in food</li> <li>■ do not use for more than 14 days unless directed by your doctor</li> </ul> <p><b>Repeated 14-Day Courses (if needed)</b></p> <ul style="list-style-type: none"> <li>■ you may repeat a 14-day course every 4 months</li> <li>■ <b>do not take for more than 14 days or more often than every 4 months unless directed by a doctor</b></li> <li>■ children under 18 years of age: ask a doctor</li> </ul>
<p><b>Ask a doctor before use if you have</b></p> <ul style="list-style-type: none"> <li>■ had heartburn over 3 months. This may be a sign of a more serious condition.</li> <li>■ heartburn with <b>lightheadedness, sweating or dizziness</b></li> <li>■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness</li> <li>■ frequent <b>chest pain</b></li> <li>■ frequent wheezing, particularly with heartburn</li> <li>■ unexplained weight loss</li> <li>■ nausea or vomiting</li> <li>■ stomach pain</li> </ul> <p><b>Ask a doctor or pharmacist before use if you are taking</b></p> <ul style="list-style-type: none"> <li>■ warfarin (blood-thinning medicine)</li> <li>■ prescription antifungal or anti-yeast medicines</li> <li>■ diazepam (anxiety medicine) ■ digoxin (heart medicine)</li> </ul>	<p><b>Other information</b></p> <ul style="list-style-type: none"> <li>■ read the directions, warnings and package insert before use</li> <li>■ keep the carton and package insert. They contain important information.</li> <li>■ store at 20-25°C (68-77°F)</li> <li>■ keep product out of high heat and humidity</li> <li>■ protect product from moisture</li> </ul> <p><b>Inactive ingredients</b> glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate</p>
<p><b>Stop use and ask a doctor if</b></p> <ul style="list-style-type: none"> <li>■ your heartburn continues or worsens</li> <li>■ you need to take this product for more than 14 days</li> <li>■ you need to take more than 1 course of treatment every 4 months</li> </ul>	<p><b>Questions? 1-800-759-4841</b></p>

Product of Sweden  
 Dist. by Procter & Gamble, Cincinnati, OH 45202  
 42431715

# 14ct Prilosec Carton



**Drug Facts (continued)**

- keep the carton and package insert. They contain important information.
- store at 20-25° C (68-77° F)
- keep product out of high heat and humidity ■ protect product from moisture

**Drug Facts (continued)**  
**Inactive ingredients** glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

**14 TABLETS**  
 One 14-day course of treatment

**omeprazole delayed-release tablets**  
**20 mg / acid reducer**

**Prilosec**

**NEW!**

**Treats Frequent Heartburn!**

**Prilosec OTC**

100% SIZE  
 12 digit UPC  
 (non-suppressed)  
 For Position Only  
 0 37000 35905 0

Safety Feature—Do not use if tablet blister unit is open or torn.

Dist. by Procter & Gamble, Cincinnati, OH 45202  
**Drug Facts (continued)**  
 Questions? 1-800-289-9181  
 Product of Sweden 95056540  
 XXXXXXXXXXXXX  
 EXP XX/XX

**Drug Facts**

**Active ingredient (in each tablet)** Omeprazole magnesium delayed-release tablet 20.6 mg (equivalent to 20 mg omeprazole).....Acid reducer

**Use**  
 ■ treats frequent heartburn (occurs **2 or more** days a week)  
 ■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**  
**Allergy alert:** Do not use if you are allergic to omeprazole  
**Do not use if you have**  
 ■ trouble or pain swallowing food  
 ■ vomiting with blood  
 ■ bloody or black stools  
 These may be signs of a serious condition. See your doctor.

**Ask a doctor before use if you have**  
 ■ had heartburn over 3 months. This may be a sign of a more serious condition.  
 ■ heartburn with **lightheadedness, sweating or dizziness**  
 ■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness  
**Frequent chest pain**  
 ■ frequent wheezing, particularly with heartburn  
 ■ unexplained weight loss  
 ■ nausea or vomiting ■ stomach pain

**Ask a doctor or pharmacist before use if you are taking**  
 ■ warfarin (blood-thinning medicine)  
 ■ prescription antitussive or anti-yeast medicines  
 ■ diazepam (anxiety medicine) ■ digoxin (heart medicine)

**Drug Facts (continued)**

**Stop use and ask a doctor if**  
 ■ your heartburn continues or worsens  
 ■ you need to take this product for more than 14 days  
 ■ you need to take more than 1 course of treatment every 4 months

**If pregnant or breast-feeding,** ask a health professional before use.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

■ adults 18 years of age and older  
 ■ this product is to be used once a day (every 24 hours), every day for 14 days  
 ■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**  
 ■ swallow 1 tablet with a glass of water before eating in the morning  
 ■ take every day for 14 days  
 ■ do not take more than 1 tablet a day  
 ■ do not chew or crush the tablets  
 ■ do not crush tablets in food  
 ■ do not use for more than 14 days unless directed by your doctor

**Repeated 14-Day Courses (if needed)**  
 ■ you may repeat a 14-day course every 4 months  
 ■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor

**Other information**  
 ■ children under 18 years of age: ask a doctor  
 ■ read the directions, warnings and package insert before use

FPO 128 code

FPO 128 code

Dist. by  
Procter  
& Gamble,  
Cincinnati,  
OH 45202

Product of Sweden 95055644  
OH 45202

**Drug Facts (continued)**  
**Questions? 1-800-289-9181**

EXP XX/XX  
XXXXXXXXXX

NDC 37000-465-02

**Treats Frequent  
Heartburn!**

**Prilosec<sup>OTC</sup>**

**NOT FOR RESALE**

**NEW!**

**Prilosec**  
*omeprazole delayed-release tablets  
20 mg / acid reducer*

**14 TABLETS**  
*One 14-day course of treatment*

**Drug Facts (continued)**

- Keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- Keep product out of high heat and humidity
- protect product from moisture

**Drug Facts (continued)**

**Inactive ingredients** glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate



**Drug Facts**

**Active ingredient (in each tablet)** **Purpose**  
Omeprazole magnesium delayed-release tablet, 20.6 mg (equivalent to 20 mg omeprazole).....Acid reducer

**Use**  
■ treats frequent heartburn (occurs 2 or more days a week)  
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**  
**Allergy alert:** Do not use if you are allergic to omeprazole

**Do not use** if you have  
■ trouble or pain swallowing food  
■ vomiting with blood  
■ bloody or black stools

These may be signs of a serious condition. See your doctor.  
**Ask a doctor before use if you have**

- heartburn with **lightheadedness, sweating or dizziness**
  - chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
  - frequent chest pain
  - frequent wheezing, particularly with heartburn
  - unexplained weight loss
  - nausea or vomiting
  - stomach pain
- Ask a doctor or pharmacist before use if you are taking**
- warfarin (blood-thinning medicine)
  - prescription antifungal or anti-yeast medicines
  - diazepam (anxiety medicine)
  - diploxin (heart medicine)

**Drug Facts (continued)**

**Stop use and ask a doctor if**  
■ your heartburn continues or worsens  
■ you need to take this product for more than 14 days  
■ you need to take more than 1 course of treatment every 4 months

**If pregnant or breastfeeding,** ask a health professional before use.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

■ adults: 18 years of age and older  
■ this product is to be used once a day (every 24 hours), every day for 14 days  
■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

**Repeated 14-Day Courses (if needed)**

- you may repeat a 14-day course every 4 months
- do not take for more than 14 days or more often than every 4 months unless directed by a doctor
- children under 18 years of age: ask a doctor

**Other information**

■ read the directions, warnings and package insert before use

**NEW!**



**Prilosec**  
OTC

Safety Feature—Do not use if tablet blister unit is open or torn.

NDC 37000-455-02

**NEW!**

**Treats Frequent  
Heartburn!**

**Prilosec**

*omeprazole delayed-release tablets  
20 mg / acid reducer*

**OTC™**

**14** TABLETS

*One 14-day course of treatment*

**Drug Facts** (continued)

- Keep the carton and package insert. They contain important information.
- store at 20-25° C (68-77° F)
- Keep product out of high heat and humidity
- protect product from moisture

**Drug Facts** (continued)

**Inactive ingredients** glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

Dist. by  
Procter  
& Gamble,  
Cincinnati,  
OH 45202

**Drug Facts** (continued)  
**Questions? 1-800-289-9181**

Product of Sweden 95055540

XXXXXXXXXX  
EXP XX/XX

## Drug Facts

### Active ingredient (in each tablet) Purpose

Omeprazole magnesium delayed-release tablet 20.6 mg  
(equivalent to 20 mg omeprazole).....Acid reducer

### Use

- treats frequent heartburn (occurs **2 or more** days a week)
- not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

### Warnings

**Allergy alert:** Do not use if you are allergic to omeprazole

**Do not use** if you have

- trouble or pain swallowing food
- vomiting with blood
- bloody or black stools

These may be signs of a serious condition. See your doctor.

### Ask a doctor before use if you have

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck or shoulders; or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting ■ stomach pain

### Ask a doctor or pharmacist before use if you are taking

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine) ■ digoxin (heart medicine)

## Drug Facts (continued)

### Stop use and ask a doctor if

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months

**If pregnant or breast-feeding**, ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

### Directions

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

### 14-Day Course of Treatment

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

### Repeated 14-Day Courses (if needed)

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor

### Other information

- read the directions, warnings and package insert before use

XXXXXXXXXX  
EXP XX/XX

Prilosec  
OTC

Dist. by Procter & Gamble, Cincinnati, OH 45202  
95055549  
Product of Sweden

NDC 37000-455-03

Treats Frequent  
Heartburn!

**Prilosec**  
omeprazole delayed-release tablets  
20 mg / acid reducer

28 TABLETS  
Two 14-day courses of treatment

**Drug Facts (continued)**

**Inactive ingredients** glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

**Questions? 1-800-289-9181**

**Drug Facts (continued)**

- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

Safety Feature—  
Do not use  
if tablet blister  
unit is open  
or torn.

Prilosec  
OTC



**Drug Facts**

**Active ingredient (in each tablet)**

Omeprazole magnesium delayed-release tablet, 20.6 mg (equivalent to 20 mg omeprazole),..... Acid reducer

**Purpose**

- Use**
- treats frequent heartburn (occurs **2 or more** days a week)
  - not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**

**Allergy alert:** Do not use if you are allergic to omeprazole

- Do not use if you have**
- trouble or pain swallowing food
  - vomiting with blood
  - bloody or black stools
- These may be signs of a serious condition. See your doctor.

**Ask a doctor before use if you have**

- had heartburn over 3 months. This may be a sign of a more serious condition.
- heartburn with **lightheadedness, sweating or dizziness**
- chest pain or shoulder pain with shortness of breath, sweating, pain spreading to arms, neck or shoulders, or lightheadedness
- frequent **chest pain**
- frequent wheezing, particularly with heartburn
- unexplained weight loss
- nausea or vomiting
- stomach pain

**Ask a doctor or pharmacist before use if you are taking**

- warfarin (blood-thinning medicine)
- prescription antifungal or anti-yeast medicines
- diazepam (anxiety medicine)
- digoxin (heart medicine)

**Drug Facts (continued)**

**Stop use and ask a doctor if**

- your heartburn continues or worsens
- you need to take this product for more than 14 days
- you need to take more than 1 course of treatment every 4 months before use.

**If pregnant or breastfeeding,** ask a health professional before use.

**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

- adults 18 years of age and older
- this product is to be used once a day (every 24 hours), every day for 14 days
- it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

- swallow 1 tablet with a glass of water before eating in the morning
- take every day for 14 days
- do not take more than 1 tablet a day
- do not chew or crush the tablets
- do not crush tablets in food
- do not use for more than 14 days unless directed by your doctor

**Repeated 14-Day Courses (if needed)**

- you may repeat a 14-day course every 4 months
- **do not take for more than 14 days or more often than every 4 months unless directed by a doctor**
- children under 18 years of age: ask a doctor

**Other information**

- read the directions, warnings and package insert before use



Prilosec  
OTC

XXXXXXXXXX  
EXP XX/XX

Product of Sweden  
Dist. by Procter & Gamble, Cincinnati, OH 45202  
95055550

Treats **Frequent Heartburn!**

# Prilosec

omeprazole delayed-release tablets  
20 mg / acid reducer

**42 TABLETS**  
Three 14-day courses of treatment

NDC-37000-455-04

Treats **Frequent Heartburn!**

# Prilosec

OTC

**42 TABLETS**  
Three 14-day courses of treatment

**NEW!**

**Drug Facts (continued)**

- keep the carton and package insert. They contain important information.
- store at 20-25°C (68-77°F)
- keep product out of high heat and humidity
- protect product from moisture

**Inactive ingredients** glyceryl monostearate, hydroxypropyl cellulose, hypromellose, iron oxide, magnesium stearate, methacrylic acid copolymer, microcrystalline cellulose, paraffin, polyethylene glycol 6000, polysorbate 80, polyvinylpyrrolidone, sodium stearyl fumarate, starch, sucrose, talc, titanium dioxide, triethyl citrate

**Questions? 1-800-289-9181**

**Safety Feature—**  
Do not use if tablet blister unit is open or torn.

100% SIZE

12 digit UPC (non-suppressed) For Position Only

37000 135907 4

# Prilosec

OTC

**Drug Facts**

**Active ingredient (in each tablet)** **Purpose**  
Omeprazole magnesium delayed-release tablet, 20.0 mg (equivalent to 20 mg omeprazole).....Acid reducer

**Use**  
■ treats frequent heartburn (occurs 2 or more days a week)  
■ not intended for immediate relief of heartburn; this drug may take 1 to 4 days for full effect

**Warnings**  
**Allergy alert:** Do not use if you are allergic to omeprazole

**Do not use** if you have  
■ trouble or pain swallowing food  
■ vomiting with blood  
■ bloody or black stools

**Ask a doctor before use if you have**  
These may be signs of a serious condition. See your doctor.  
■ had heartburn over 3 months. This may be a sign of a more serious condition.

**Ask a doctor before use if you are taking**  
■ heartburn with **lightheadedness, sweating or dizziness**  
■ chest pain or shoulder pain with shortness of breath; sweating; pain spreading to arms, neck, or shoulders or lightheadedness  
■ frequent **chest pain**  
■ frequent wheezing, particularly with heartburn  
■ unexplained weight loss  
■ nausea or vomiting ■ stomach pain

**Ask a doctor or pharmacist before use if you are taking**  
■ warfarin (blood-thinning medicine)  
■ prescription antifungal or anti-yeast medicines  
■ diazepam (anxiety medicine) ■ digoxin (heart medicine)

**Drug Facts (continued)**

**Stop use and ask a doctor if**  
■ your heartburn continues or worsens  
■ you need to take this product for more than 14 days  
■ you need to take more than 1 course of treatment every 4 months  
■ you need to take more than 1 course of treatment every 4 months before use.

**If pregnant or breast-feeding,** ask a health professional before use.  
**Keep out of reach of children.** In case of overdose, get medical help or contact a Poison Control Center right away.

**Directions**

■ adults 18 years of age and older  
■ this product is to be used once a day (every 24 hours), every day for 14 days  
■ it may take 1 to 4 days for full effect, although some people get complete relief of symptoms within 24 hours

**14-Day Course of Treatment**

■ swallow 1 tablet with a glass of water before eating in the morning  
■ take every day for 14 days  
■ do not take more than 1 tablet a day  
■ do not chew or crush the tablets  
■ do not crush tablets in food  
■ do not use for more than 14 days unless directed by your doctor

**Repeated 14-Day Courses (if needed)**

■ you may repeat a 14-day course every 4 months  
■ do not take for more than 14 days or more often than every 4 months unless directed by a doctor  
■ children under 18 years of age: ask a doctor

**Other information**

■ read the directions, warnings and package insert before use

FPO 128 code

FPO 128 code

PHA421D4k 42ct carton  
6-19-03  
Laser Output @ 100%

P&G 077  
P&G 137  
P&G 084  
P&G 055

